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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,447	07/14/2006	Peter Jan Leonard Mario Quaedflieg	4662-177	2419

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NIXON & VANDERHYE, PC
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EXAMINER

CHANDRAKUMAR, NIZAL S

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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10/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p style="text-align: center;">Office Action Summary</p>	<p>Application No.</p> <p>10/576,447</p>	<p>Applicant(s)</p> <p>QUAEDFLIEG ET AL.</p>	
	<p>Examiner</p> <p>Nizal S. Chandrakumar</p>	<p>Art Unit</p> <p>1625</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

This application filed 07/14/2006 is the US national phase of international application PCT/EP2004/012064 filed 25 October 2004, which designated the U.S. and claims benefit of 15P 03078392.2, dated 28 October 2003.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed oxidation using TEMPO, does not reasonably provide enablement for the generically claimed TEMPO-derivative of formula 1. The formula 1 encompasses many structures containing many functionalities as well as Y variables, whereas the TEMPO has no functionality other than simple alkyl groups at the 2 and 6 positions of the piperidine base core structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

- 1) The breadth of the claims,
- 2) The nature of the invention,
- 3) The state of the prior art,
- 4) The level of one of ordinary skill,
- 5) The level of predictability in the art,
- 6) The amount of direction provided by the inventor,
- 7) The existence of working examples,
- 8) The quantity of experimentation needed to make or use the invention based on the content of the

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disclosure.

While all the above factors were considered, some of the specific considerations are described below:

The breadth of the claims: The formula 1 of the Tempo reagent has several substituents, which also have stereo centers making the conceivable number of possible structures encompassed by the formula large. In addition, the Y variable includes three forms of the active agent.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the art of organic chemistry, it is noted that each embodiment of the invention (tempo derivatives) is required to be individually assessed for viability.

The state and the predictability of the art and the amount of guidance and working examples: The art of organic chemistry is unpredictable and success in any given chemical transformation depends on many variables including the nature of the reagent.

The working examples presented in the specification are limited to TEMPO. It is not seen where in the specification the applicability of other derivatives for the oxidation is demonstrated.

Though the oxidation of alcohols by TEMP O is well known, because of the sensitivity of the particular alcohol Solketals substrate, it is unpredictable whether the claimed efficiency with TEMPO will obtain when TEMPO derivatives are used in place of TEMPO.

The existence of such unpredictabilities establishes that the contemporary knowledge regarding the sensitive nature of Solketals s towards oxidizing agents, would prevent one of ordinary skill in the art from accepting the claimed processes demonstrated with one particular radical TEMPO as universally applicable for all the conceivable structures of formula 1.

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Further, the specification does not provide adequate citations (commercial or literature) for procuring the starting materials needed for making many of the claimed compounds of formula 1.

The quantity of experimentation needed: In the instant case, there is a substantial gap between the guidance provided and the breadth of the claims. Given the direction and working Examples provided in the specification, in order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. The guidance provided in the specification is limited. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

In conclusion, based on the evidence regarding each of the above mentioned Wands factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

What is enabled is the use of TEMPO for the oxidation of Solketals.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0775684 A1, which discloses the process of oxidation of alcohols to the corresponding aldehydes and ketones using TCCA and an oxidant in the presence of TEMPO or a derivative of TEMPO as catalyst.

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5. The difference is that the prior art does not specifically mention the process for the oxidation of 2,2-dimethyl-1,3-dioxolane-4-yl-methanol.

The availability of many reagents including TEMPO for the oxidation of alcohols to aldehydes is well known. One skilled in the art of organic chemistry, exploring efficient methods of oxidizing Solketals would be motivated to try many of these reagents. The instantly claimed invention of using TEMPO would have been suggested because of the teachings of EP 0775684 A1. A strong case of *prima facie* obviousness has been established.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nizal S. Chandrakumar whose telephone number is 571-272-6202. The examiner can normally be reached on 8.30 am – 5 pm Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached at 571-272-0867 or Primary Examiner D. Margaret Seaman can be reached at 571-272-0694. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nizal S. Chandrakumar



D. MARGARET SEAMAN
PRIMARY EXAMINER